

Where the relationships are more subtle and not readily recognized, the purchasing agent may request an opinion by writing to the Food and Drug Administration at the address shown in paragraph (e) of this section.

(e) Interested parties may submit to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, the names of drug products, and of their manufacturers or distributors, that should be the subject of the same purchasing and regulatory policies as those reviewed by the Drug Efficacy Study Group. Appropriate action, including referral to purchasing officials of various government agencies, will be taken.

(f) This regulation does not apply to OTC drugs identical, similar, or related to a drug in the Drug Efficacy Study unless there has been or is notification in the FEDERAL REGISTER that a drug will not be subject to an OTC panel review pursuant to §§ 330.10, 330.11, and 330.5 of this chapter.

[39 FR 11680, Mar. 29, 1974, as amended at 48 FR 2755, Jan. 21, 1983; 50 FR 8996, Mar. 6, 1985; 55 FR 11578, Mar. 29, 1990; 74 FR 13113, Mar. 26, 2009]

### Subpart B—Specific Administrative Rulings and Decisions

#### § 310.100 New drug status opinions; statement of policy.

(a) Over the years since 1938 the Food and Drug Administration has given informal advice to inquirers as to the new drug status of preparations. These drugs have sometimes been identified only by general statements of composition. Generally, such informal opinions were incorporated in letters that did not explicitly relate all of the necessary conditions and qualifications such as the quantitative formula for the drug and the conditions under which it was prescribed, recommended, or suggested. This has contributed to misunderstanding and misinterpretation of such opinions.

(b) These informal opinions that an article is “not a new drug” or “no longer a new drug” require reexamination under the Kefauver-Harris Act (Public Law 87-781; 76 Stat. 788-89). In

particular, when approval of a new drug application is withdrawn under provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act, a drug generally recognized as safe may become a “new drug” within the meaning of section 201(p) of said act as amended by the Kefauver-Harris Act on October 10, 1962. This is of special importance by reason of proposed actions to withdraw approval of new drug applications for lack of substantial evidence of effectiveness as a result of reports of the National Academy of Sciences—National Research Council on its review of drug effectiveness; for example, see the notice published in the FEDERAL REGISTER of January 23, 1968 (33 FR 818), regarding rutin, quercetin, et al.

(c) Any marketed drug is a “new drug” if any labeling change made after October 9, 1962, recommends or suggests new conditions of use under which the drug is not generally recognized as safe and effective by qualified experts. Undisclosed or unreported side effects as well as the emergence of new knowledge presenting questions with respect to the safety or effectiveness of a drug may result in its becoming a “new drug” even though it was previously considered “not a new drug.” Any previously given informal advice that an article is “not a new drug” does not apply to such an article if it has been changed in formulation, manufacture control, or labeling in a way that may significantly affect the safety of the drug.

(d) For these reasons, all opinions previously given by the Food and Drug Administration to the effect that an article is “not a new drug” or is “no longer a new drug” are hereby revoked. This does not mean that all articles that were the subjects of such prior opinions will be regarded as new drugs. The prior opinions will be replaced by opinions of the Food and Drug Administration that are qualified and current on when an article is “not a new drug,” as set forth in this subchapter.

[39 FR 11680, Mar. 29, 1974]